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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/530,112	07/10/1995	KENICHI MATSUBARA	215/070	4858

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EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/17/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/530,112

Applicant(s)

MATSUBARA ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,13,21 and 29-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 13, 21, 29-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-4-02 has been entered.
2. Response filed 11-13-00 has been entered.
3. Claims 1, 3, 13, 21, and 29-68 are pending in the instant application.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for reasons of record set forth in the previous office action of 5-9-2000 and 3-7-01.

Response to Arguments

Applicant's arguments filed 6-4-02 have been fully considered but they are not persuasive.

Applicants have argued that examiner is incorrect that the function of encoded proteins would be needed and that for uses such as characterization of disease state, the differential expression of particular genes or gene expression pattern provide the information without a requirement for knowledge of the function of particular genes. However, as discussed in previous office actions of 5-9-00 and 3-7-01, it is reiterated that neither the specification does not teach as to the expression of what genes or what disease states can be characterized using the claimed sequences. Additionally, there is no teaching in the specification to indicate specific association of the claimed sequences to any disease state.

Therefore, in the absence of any knowledge of the function of the protein encoded by the claimed polynucleotides or association of the sequences to a disease state, the probes and primers and gene mapping would be used to carry out further research on the claimed polynucleotide itself, to further define its function, location on the chromosome and expression pattern in a cell or tissue, etc. Same will be true about disease effects, cell or developmental differences, biological function because in the absence of any teachings about the function of the encoded protein, and thus, all the argued uses will be to further study the invention itself and characterize it. Applicants arguments, that the present invention provides tools for work with cells, tissues and diseases or pathological conditions and therefore, analogy with laboratory equipment is correct, are not persuasive because in the absence of any knowledge of the protein encoded, function of the protein or relationship of the encoded protein or claimed sequences to a disease, there will not be any patentable utility.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3, 13 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office actions of 3-7-01, 5-9-00 and 8-16-99.

R sponse to Arguments

Applicant's arguments filed 6-4-02 have been fully considered but they are not persuasive to obviate the rejection of all the claims. It is noted the rejection of claims 29-68 that recite "consists of" is withdrawn.

Applicants have argued that the issue is not whether the nucleotide sequence of complete cDNAs is provided, but instead whether the specification provides sufficient identifying characteristics of the cDNAs and since applicants have provide unique identifying sequences they have provided unequivocal identification of the corresponding cDNAs. However, Applicants have ignored the issue that the partial sequences of the cDNAs disclosed in the specification are not the complete structure. Additionally, other identifying characteristics of the sequences have not been described. The sequences disclosed in the specification are only partial structure, not the complete structure. Examiner has raised that the specification does not teach the complete structure of any full-length cDNA or gene, nor are any other identifying characteristics disclosed. Applicants argument examiner has not provided any reasons as to why applicants were not in possession of claimed sequences is not persuasive because the claimed sequences are not full length sequences, just part of sequences. It is noted that claim 1 recites **a purified single stranded DNA comprising** the sequence disclosed in SEQ ID Nos. Accordingly, claim 1 recites a genus, which will include full length sequences and other sequences that will comprise the SEQ ID NO. Therefore, just the description of the sequence of the SEQ ID Nos is not sufficient to describe the entire genus. Applicants have not provided any evidence as to how a particular SEQ ID NO shows the possession of the entire genus of sequences.

8. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the rejection under 35 USC § 101 in paragraph 5 and in the office action of 5-9-00, one skilled in the art clearly would not know how to use the claimed invention.

In the event that Applicants might overcome rejection under 35 USC § 101, the 112 first paragraph rejection set forth in the office action of 3-7-01, 5-9-00 and 8-16-99 limiting the scope of the enabled invention to elected sequences and fragments thereof would still apply as discussed below.

9. Claims 1, 3, 13, 21, and 29-68 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to polynucleotides consisting of the elected sequences, or fragments thereof, does not reasonably provide enablement for other claims and embodiments for reasons of record set forth in the previous office actions of 3-7-01, 5-9-00 and 8-16-99.

Applicants have not responded to the enablement rejections.

10. No claim is allowed.

Action Is Final, First Action Following Request for Continued Examination
under 37 CFR 1.114 All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a) A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Tiffiany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D.
PATENT EXAMINER